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PATENT COOPERATION TREATY

To:

HETERO DRUGS LIMITED
Hetero House, 8-3-166/7/1, Erragadda,
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PCT

REC'D 09 DEC 2005

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing 6 December 2005 (06.12.2005)
(day/month/year)

Applicant's or agent's file reference
HDL-PCT-28

FOR FURTHER ACTION

See paragraph 2 below

International application No.
PCT/IN 2005/000097

International filing date (day/month/year)
1 April 2005 (01.04.2005)

Priority Date (day/month/year)

International Patent Classification (IPC) or both national classification and IPC
C07D 401/00, A61K 31/445

Applicant

HETERO DRUGS LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Cont. No. I Basis of the opinion
- ☐ Cont. No. II Priority
- ☒ Cont. No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Cont. No. IV Lack of unity of invention
- ☒ Cont. No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Cont. No. VI Certain documents cited
- ☐ Cont. No. VII Certain defects in the international application
- ☒ Cont. No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ AT
Austrian Patent Office
Dresdner Straße 87, A-1200 Vienna

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Authorized officer

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Continuation No. I

Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed.

Continuation No. III:

**Non-establishment of opinion with regard to
novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of the said claims Nos. 5 because said claims Nos. 5 relate to the following subject matter which does not require an international preliminary examination (specify):

Claim 5 refers to parts of the description (figure 3), only and does not comprise any technical inventive feature.;

no international search report has been established for said claims Nos. 5.

Continuation No. V

**Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step
or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims 1-4, 6-11	YES
	Claims ----	NO
Inventive step (IS)	Claims 1-4, 6-11	YES
	Claims ----	NO
Industrial applicability (IA)	Claims 1-4, 6-11	YES
	Claims ----	NO

2. Citations and explanations:

In the light of the cited prior art documents the present application is considered to meet both requirements, novelty and inventive step, since:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IN 2005/000097

- A crystalline form B of rupatadine characterized by the physical features given in claims 1-4 or a process for the preparation of such a crystalline form of rupatadine by stirring rupatadine in a suspension of a certain apolar organic solvent according to claims 6-10 are not known from prior art nor is a pharmaceutical composition comprising this new crystalline form B of rupatadine.
- There could not be derived any suggestion from the (combined) teachings of prior art, that rupatadine could exist in different crystalline forms having totally different physical properties (e.g. a melting point of form B being about twice as high as that of the crystalline form known from prior art).

Industrial applicability of the subject matter of claims 1-4 and 6-11 is obviously given.

Continuation No. VIII:

Certain observations on the international application


The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:


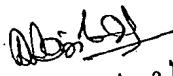
Claim 11 should be restricted to pharmaceutical compositions wherein the acceptable carrier or diluent is not a liquid, since in liquid media/solution the particular crystalline form B of rupatadine is no longer present.

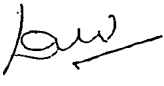
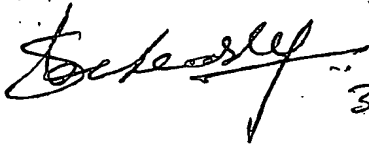
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VIII-4-1	<p>Declaration: Inventorship (only for the purposes of the designation of the United States of America) Declaration of Inventorship (Rules 4.17(iv) and 51bis.1(a)(iv)) for the purposes of the designation of the United States of America:</p>	<p>I hereby declare that I believe I am the original, first and sole (if only one inventor is listed below) or joint (if more than one inventor is listed below) inventor of the subject matter which is claimed and for which a patent is sought.</p> <p>This declaration is directed to the international application of which it forms a part (if filing declaration with application).</p> <p>I hereby declare that my residence, mailing address, and citizenship are as stated next to my name.</p> <p>I hereby state that I have reviewed and understand the contents of the above-identified international application, including the claims of said application. I have identified in the request of said application, in compliance with PCT Rule 4.10, any claim to foreign priority, and I have identified below, under the heading "Prior Applications", by application number, country or Member of the World Trade Organization, day, month, and year of filing, any application for a patent or inventor's certificate filed in a country other than the United States of America, including any PCT international application designating at least one country other than the United States of America, having a filing date before that of the application on which foreign priority is claimed.</p>
VIII-4-1-1	Prior applications:	

Original (for SUBMISSION)

		<p>I hereby acknowledge the duty to disclose information that is known by me to be material to patentability as defined by 37 C.F.R. § 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the PCT international filing date of the continuation-in-part application. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.</p>
VIII-4-1-1-1	Name (LAST, First)	PARTHASARADHI REDDY, bandi
VIII-4-1-1-2	Residence: (city and either US State, if applicable, or country)	Hyderabad, India
VIII-4-1-1-3	Mailing address:	Hetero House, 8-3-166/7/1, Erragadda, Hyderabad, Andhrapradesh 500018 Hyderabad India
VIII-4-1-1-4	Citizenship:	IN
VIII-4-1-1-5	Inventor's Signature: (if not contained in the request, or if declaration is corrected or added under Rule 26ter after the filing of the international application. The signature must be that of the inventor, not that of the agent)	
VIII-4-1-1-6	Date: (of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26ter after the filing of the international application)	30-03-2005

VIII-4-1-2-1	Name (LAST, First)	RATHNAKAR REDDY, kura
VIII-4-1-2-2	Residence: (city and either US State, if applicable, or country)	Hyderabad, India
VIII-4-1-2-3	Mailing address:	Hetero Drugs Limited (R & D), Plot No. B-80 & 81, A.P.I.E., Balanagar 500018 Hyderabad India
VIII-4-1-2-4	Citizenship:	IN
VIII-4-1-2-5	Inventor's Signature: (if not contained in the request, or if declaration is corrected or added under Rule 26ter after the filing of the international application. The signature must be that of the inventor, not that of the agent)	
VIII-4-1-2-6	Date (of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26ter after the filing of the international application)	30/03/2005.
VIII-4-1-3-1	Name (LAST, First)	RAJI REDDY, rapolu
VIII-4-1-3-2	Residence: (city and either US State, if applicable, or country)	Hyderabad, India
VIII-4-1-3-3	Mailing address:	Hetero Drugs Limited (R & D), Plot No. B-80 & 81, A.P.I.E., Balanagar 500018 Hyderabad India
VIII-4-1-3-4	Citizenship:	IN
VIII-4-1-3-5	Inventor's Signature: (if not contained in the request, or if declaration is corrected or added under Rule 26ter after the filing of the international application. The signature must be that of the inventor, not that of the agent)	
VIII-4-1-3-6	Date (of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26ter after the filing of the international application)	30/03/2005

VIII-4-1-4-1	Name (LAST, First)	MURALIDHARA REDDY, dasari
VIII-4-1-4-2	Residence: (city and either US State, if applicable, or country)	Hyderabad, India
VIII-4-1-4-3	Mailing address:	Hetero Drugs Limited (R & D), Plot No. B-80 & 81, A.P.I.E., Balanagar 500018 Hyderabad India
VIII-4-1-4-4	Citizenship:	IN
VIII-4-1-4-5	Inventor's Signature: (if not contained in the request, or if declaration is corrected or added under Rule 26ter after the filing of the international application. The signature must be that of the inventor, not that of the agent)	
VIII-4-1-4-6	Date (of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26ter after the filing of the international application)	30/3/05
VIII-4-1-5-1	Name (LAST, First)	SUBASH CHANDER REDDY, kesireddy
VIII-4-1-5-2	Residence: (city and either US State, if applicable, or country)	Hyderabad, India
VIII-4-1-5-3	Mailing address:	Hetero Drugs Limited (R & D), Plot No. B-80 & 81, A.P.I.E., Balanagar 500018 Hyderabad India
VIII-4-1-5-4	Citizenship:	IN
VIII-4-1-5-5	Inventor's Signature: (if not contained in the request, or if declaration is corrected or added under Rule 26ter after the filing of the international application. The signature must be that of the inventor, not that of the agent)	
VIII-4-1-5-6	Date (of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26ter after the filing of the international application)	30/03/2005

VIII-2-1	Declaration: Entitlement to apply for and be granted a patent Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent (Rules 4.17(II) and 51bis.1(a)(II)), in a case where the declaration under Rule 4.17(iv) is not appropriate: Name (LAST, First)	in relation to this international application HETERO DRUGS LIMITED is entitled to apply for and be granted a patent by virtue of the following:
VIII-2-1(i)		HETERO DRUGS LIMITED is entitled as employer of the inventor, PARTHASARADHI REDDY, bandi
VIII-2-1(i)		HETERO DRUGS LIMITED is entitled as employer of the inventor, RATHNAKAR REDDY, kura
VIII-2-1(i)		HETERO DRUGS LIMITED is entitled as employer of the inventor, RAJI REDDY, rapolu
VIII-2-1(i)		HETERO DRUGS LIMITED is entitled as employer of the inventor, MURALIDHARA REDDY, dasari
VIII-2-1(i)		HETERO DRUGS LIMITED is entitled as employer of the inventor, SUBASH CHANDER REDDY, kesireddy
VIII-2-1(i)	This declaration is made for the purposes of:	all designations except the designation of the United States of America